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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. ¹⁶
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EXAMINER

ART UNIT	PAPER NUMBER ⁸
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/490,208

Applicant(s)

Bennett et al

Examiner

Sean McGarry

Group Art Unit

1635



X Responsive to communication(s) filed on May 17, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) 15-20 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

X Claim(s) 1, 2, and 4-14 is/are rejected.

X Claim(s) 3 is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received:

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

X Notice of References Cited, PTO-892

X Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

SEE OFFICE ACTION ON THE FOLLOWING PAGES

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DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-14, in Paper No. 6, filed 5/17/00, is acknowledged. The traversal is on the ground(s) that a search of the antisense oligonucleotides would necessarily reveal prior art on therapeutic uses. This is not found persuasive because the search for Group I would encompass a search of 435/6, 536/23.2, 536/24.1 while a search for Group II would embrace a search of 514/44, for example. Further the search of an antisense oligonucleotide would not necessarily embrace a search for therapeutic antisense methods since therapeutic methods utilizing antisense oligonucleotides would not necessarily include the specific antisense molecules instantly claimed.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 15-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 6.

3. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 10 recites "...wherein the antisense oligonucleotide is. . .". There is a lack of antecedent basis for this limitation.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Leesoon-Wood et al [Proceedings of the Amer. Assoc. For Cancer Research Vol. 37(0):145, 1996].

Leesoon-Wood et al disclose the inhibition of C3H 10T1/2 cells via the administration of 15mer antisense oligonucleotides targeted to iNOS mRNA.

6. Claims 1, 2, 4, 5, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Peresleni et al [Applicant's form 1449 citation AT].

Peresleni et al disclose a phosphorothioate antisense oligomer targeted to the 5' UTR/initiation codon/ region of human iNOS mRNA and disclose the inhibition of human iNOS in BSC-1 kidney tubular epithelial cells (see abstract and page 972, for example).

7. Claims 1, 2, 4, 5, 11, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ding et al [Applicant's form 1449 citation AG].

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Ding et al disclose a 21mer phosphorothioate antisense oligonucleotide targeted to bases 1-21 of the murine iNOS mRNA and disclose the administration of said oligonucleotide to SJL/J mice as an animal model for multiple sclerosis via injection with a sterile saline solution.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 6-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al, Peresleni et al, and Leeson-Wood et al in view of Monia et al. [US Patent No. 5,872,242].

Ding et al, Peresleni et al, and Leeson-Wood et al are relied upon as above and further these references teach the implications of iNOS in pathological conditions and the benefits of

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inhibiting the expression of iNOS to determine the possible role of iNOS in such pathological conditions.

None of these references specifically disclose antisense oligonucleotides comprising modified sugar moieties or modified nucleobases, chimeric antisense oligonucleotides or a colloidal dispersion system.

Monia et al have taught antisense oligonucleotides comprising modified sugar moieties, antisense oligonucleotides comprising modified nucleobases, chimeric antisense oligonucleotides and modes of delivery such as cholesterol or other lipid moieties. At columns 6-9 these limitations have been taught in general and specifically where the benefits of these modifications in antisense techniques has been taught.

Since Ding et al, Peresleni et al, and Leeson-Wood et al have taught the implications of iNOS in pathological conditions and the benefits of inhibiting the expression of iNOS to determine the possible role of iNOS in such pathological conditions via antisense techniques and Monia et al have taught the specific modifications and there benefits in antisense techniques it would have been obvious to combine the teachings of these references to make the instant invention.

The invention as a whole would therefore have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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10. Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean McGarry whose telephone number is (703) 305-7028.

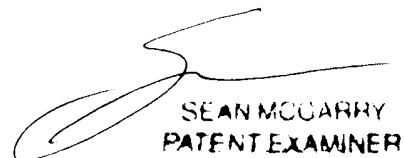
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. Papers should be faxed to Art Unit 1635 via the PTO Technology Center Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see C.F.R. 1.6(d)). The Art Unit 1635 FAX number is (703) 308-4242 or (703) 305-3014. NOTE: If Applicant **does** submit a paper by Fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Sean McGarry

July 26, 2000



SEAN MCGARRY
PATENT EXAMINER

Technology Center 1600